K093211

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JUN - 3 2010

V. 510(k) Summary of Safety and Effectiveness

CareCenter MD (Electrocardiograph)

General Information

Criteria	*Information*
Trade Name	CareCenter MD
Model Name	CareCenter MD, Resting ECG, USB CareCenter MD, Resting ECG, BT CareCenter MD, Stress-Resting ECG, USB CareCenter MD, Stress-Resting ECG, BT
Common Name	Electrocardiograph
Classification	21 CFR 870.2340 - Electrocardiograph; Class II; Product Code: DPS
510(k) Submitter	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021-8969
Contact Person	Bev Magrane, Senior Manager RA/RC Cardiac Science Corporation bmagrane@cardiacscience.com 425.402.2365 (phone) 425.402.2017 (fax)
Date Prepared	October 7, 2009

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent device*	*510(k)*
Reynolds Medical Ltd. Herts England	CardioDirect ECG	K024283
GE Medical Systems Information Technologies Milwaukee, WI	CardioSoft/CASE Cardiac Testing System	K031561
ET Medical Devices Spa, Milan, Italy	Cardioline AR600	K051534
Mortara Instrument, Inc. Milwaukee, WI	X-12 Telemetry Module ECG	K974149

Predicate Device Comparison Summary:

The CareCenter MD has in many instances, identical or nearly identical technological characteristics to the substantially equivalent devices. The following many ***similarities*** are noted for reference:

- Devices are all electrocardiographs.
- Devices are all classified by FDA as Class II medical devices.
- Devices have a common configuration - ECG data acquisition units, software for ECG processing, etc.
- Devices have wired and/or wireless ECG data transmission.
- Devices all have the same intended use - collect electrocardiograph (ECG) data.
- Have similar and/or nearly identical indications for use.
- Same device users - physicians and/or medical personnel.
- All have the same use environment - in medical settings.
- All are prescription use devices; no over-the-counter use.
- Are used for stress and/or resting ECG data collection.
- All have the same intended patient population - use in adults and/or pediatrics.
- Are capable of interfacing with other equipment (such as computers, etc.)
- Are similarly sized - small and lightweight.
- Units are battery and/or line-powered.
- All have ECG signal processing in accordance with technical standards and similar signal processing parameters (e.g., filters, gain, etc.).
- All have 12-lead capability.
- Some units also have arrhythmia detection, with common or identical analysis algorithms.
- Devices have similar or identical hardware characteristics (e.g., PC compatibility).
- Units all have ECG amplifiers and identical or nearly identical characteristics (e.g., input protection against defibrillation shocks, type CF applied part, simultaneous acquisition of input data from all lead channels, etc.).
- All have similar ECG display characteristics (e.g., channels displayed, stress or resting ECG, etc.).
- The majority of the devices display the ECG on the device user's personal computer (PC)
- Devices have comparable environmental operating parameters (e.g., temperature, humidity, etc.).
- All devices conform to numerous technical standards.

Therefore, due to similar or nearly identical nature of the CareCenter MD to the predicate devices in the many characteristics listed above, Cardiac Science believes the CareCenter MD is substantially equivalent to the predicate devices.

Summary of Substantial Equivalence

The Cardiac Science CareCenter MD does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed electrocardiographs that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

Device Description

The Cardiac Science *CareCenter MD* is a medical device system comprised of software and hardware acquisition modules used for acquisition, evaluation and administration of 12-channel electrocardiograph (ECG) from patients both at rest and during exercise (stress testing). The Cardiac Science *CareCenter MD* software is installed on a customer provided personal computer (PC).

CareCenter MD is a diagnostic device capable of ECG monitoring; ST analysis and arrhythmia detection; generation, review, and storage of stress reports; interpretation of resting ECG reports; and treadmill or ergometer control. Approved serial devices such as non-invasive blood pressure measurement are supported by CareCenter MD for stress testing.

Indications For Use

The Cardiac Science CareCenter MD is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner on adult and pediatric populations. The device is designed to acquire, display, process, record, analyze and output 12 lead ECG data during periods of physiological stress, induced through exercise or pharmacological means or during resting ECG testing. In addition, the CareCenter MD provides interfaces for acquiring physiological data from ancillary devices (such as spirometry and blood pressure) and records ECG in real time with and without arrhythmia detection.

The system provides automatic interpretation of resting ECG on adult populations. No automatic interpretation of resting ECGs is provided for pediatric populations. Interpretive statements should be overviewed and approved by trained physicians.

The CareCenter MD may provide interfaces for the control of external devices such as a treadmill or an ergometer, and for communicating with centralized computer systems via a network. The device is intended to provide non-diagnostic patient data management functions as both a self-contained, stand-alone application and by interfacing with Electronic Medical Records systems.

The device is not intended to be used as a vital signs or long term physiological monitor. The CareCenter MD is not intended to be used as a transport device.

Functional and Safety Testing

Device components underwent safety and bench testing on both hardware and software and demonstrated acceptable functional and performance results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardiac Science Corporation
c/o Ms. Theresa Myers
Manager, Regulatory Affairs CMD
3303 Monte Villa Parkway
Bothell, WA 98021-8969

JUN – 3 2010

Re: K093211
Trade/Device Name: CareCenter MD with Models:
CareCenter MD, Resting ECG, USB;
CareCenter MD, Resting ECG, BT;
CareCenter MD, Stress-Resting, USB; and
CareCenter MD, Stress-Resting, BT
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: April 1, 2010
Received: April 2, 2010

Dear Ms. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use Statement

510(k) Number (if known): K093211

Device Name: CareCenter MD

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093211